

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License, Inter-Institutional Agreement-Institution Lead: Biomarkers and Immunogenic Compositions for Filarial Parasites

AGENCY: National Institutes of Health, National Institute of Allergy and Infectious Diseases, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to New York Blood Center, Inc. ("NYBC"), located in New York, New York, in its rights to the technologies and patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive License should be directed to: Theodoric Mattes, Ph.D., Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane,

Suite 6D, MSC9804, Rockville, MD 20852-9804, phone number 240-627-3827, or theodoric.mattes@nih.gov.

patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to NYBC: United States Provisional Patent Application Number 62/317,342, filed May 1, 2016, the title of which is "Biomarkers and Immunogenic Compositions for Filarial Parasites" (HHS Reference No. E-288-2016-0-US-01); PCT Patent Application Number PCT/US2017/025554, filed March 31, 2017, the title of which is "Biomarkers and Immunogenic Compositions for Filarial Parasites" (HHS Reference No. E-288-2016-00-PCT-02); United States Patent Application Number 16/090,013, filed September 28, 2018, the title of which is "Biomarkers and Immunogenic Compositions for Filarial Parasites" (HHS Reference No. E-288-2016-0-US-03); and United States Patent Application Number 17/076,616, filed October 21, 2020, the title of which is "Biomarkers and Immunogenic Compositions for Filarial Parasites" (HHS Reference No. E-288-2016-0-US-04).

The patent rights to this technology have been assigned to New York Blood Center,
Inc. and the Government of the United States of America as represented by the Secretary,
Department of Health & Human Services, by each institution's respective inventors.

The prospective patent license will be for the purpose of consolidating the patent rights to New York Blood Center, Inc., for the development and commercialization of the technology.

Consolidation of these co-owned rights is intended to expedite development of the technology, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200–212.

The prospective interinstitutional agreement may include an exclusive license for NIAID's rights in these jointly owned patents. It will be sublicensable, and any

sublicenses granted by NYBC will be subject to the provisions of 37 CFR part 404.

NIAID will retain its rights to non-exclusively license its rights to the patent applications

to third parties for internal research use.

In the subject technology, researchers at NIAID and NYBC isolated and analyzed the

transcriptome and proteome of the parasite at various life stages as well as its Wolbachia

sp. endosymbiont to identify potential biomarkers for diagnostic assays and vaccine

candidates. In all, they identified forty-seven (47) biomarkers. The associated patents

claim the use of two or more of these biomarkers in conjunction with an adjuvant as an

immunological composition, or the detection of any of these biomarkers in a serological-

type assay.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The

prospective exclusive license will be royalty bearing, and may be granted unless within

fifteen (15) days from the date of this published notice the National Institute of Allergy

and Infectious Diseases receives written evidence and argument that establishes that the

grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and

37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments

and objections, other than those in the form of a license application, will not be treated

confidentially, and may be made publicly available.

Complete license applications submitted in response to this Notice will be presumed

to contain business confidential information and any release of information in these

license applications will be made only as required and upon a request under the Freedom

of Information Act, 5 U.S.C. 552.

Dated: June 25, 2021.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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